REMARKS

Reconsideration of the subject patent application is respectfully requested.

The non-final Office Action is dated January 12, 2010 and a one (1) month extension of time for response has been requested. Claims 50-55 and 61-63 are currently pending. Claim 1-49 and 56-60 have been canceled. The current rejections of claims 50-55 and 61-63 are being addressed by amendment and further remarks which Applicants believe should be persuasive.

The Examiner has also raised 35 U.S.C. § 112 issues and these have been addressed by the claim amendments. Although these issues were previously raised by the Examiner, Applicants had a slightly different opinion as to one issue and inadvertently failed to fully address the other issue in the prior Response. Applicants appreciate the Examiner's patience in this regard and believe that both §112 issues have now been fully addressed.

As for the claim rejections, claims 50-55 and 63 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hainfeld et al. (US 5,360,895). Claims 61 and 62 are rejected under 35 U.S.C. § 102(b) as being anticipated by Peschel et al. (a 1995 publication). The Examiner further states that this rejection is also applied to claims 50, 51, and 63.

In response, claims 50, 52, 53, 61, 62, and 63 are currently amended. First, terms such as "derivatives" and "prophylactic" have been deleted. Secondly, the intended use of the recited formulations for treatment has been clarified by the addition of the phrase

"formulated for". Applicants consider that these amending changes place claims 50-55 and 61-63 in condition for allowance. By specifically addressing the 35 U.S.C. § 112 issues raised by the Examiner and by reciting the intended use for the formulation, the only remaining issue is what scope or interpretation would be appropriate to be given to the cited prior art. In this regard, the Examiner is respectfully requested to consider the following.

Hainfeld et al. (US 5,360,895)

This reference refers to antibody- or antibody fragment-gold-cluster conjugates wherein the conjugate size can be as small as 5.0 nm. Methods and reagents are disclosed in which antibodies or fragments thereof are covalently bound to a stable cluster of gold atoms. The gold cluster may contain 6, 8, 9, 11, 13, 55 or 67 gold atoms in the inner core (see for example the Abstract of Hainfeld et al.).

Thus, the Hainfeld et al. reference explicitly refers to antibody- or antibody fragment-gold-cluster conjugates, whereas the claimed formulation for treatment discloses the use of the specially selected gold-clusters with specially selected ligands as antitumor agents.

The gold-cluster $Au_{55}[PPh_3]_{12}Cl_6$ as shown in Example 16 of Hainfeld et al. is merely a starting material, i.e. a precursor for the preparation of the antibody- or antibody fragment-gold-cluster conjugates. The preparation of the above-mentioned gold-cluster in Example 16 of Hainfeld et al. is just the first step in a subsequent four-step-synthesis which leads to the desired antibody- or antibody fragment-gold-cluster conjugates. This four-step process includes the following:

(i) Preparation of $Au_{55}[PPh_3]_{12}Cl_6$ (Example 16)

(ii) Preparation of derivatized Au_{55} clusters (Example 17)

In this step a number of triphenylphosphine ligands of the compound prepared in Example 16 is replaced by biocompatible phosphines.

(iii) Activation of derivatized Au_{55} clusters for protein labeling (Example 18)

The derivatized Au_{55} clusters prepared in Example 17 are reacted with heterofunctional coupling agents to yield an activated cluster which might be coupled to proteins.

(iv) Coupling of activated clusters to proteins (Example 19)

Coupling of the activated cluster to proteins, especially to antibodies, provides the diagnostic or therapeutic agent according to Hainfeld et al.

Therefore, the Hainfeld et al. reference does not disclose the use of specially selected gold-clusters for use as antitumor agents, but rather only shows the use of antibody-metal-cluster conjugates in diagnosis and therapy.

The Hainfeld et al. reference actually teaches away from the claimed formulation for treatment since, according to Hainfeld et al., the phosphine containing gold-clusters have to be derivatized with biocompatible phosphines, activated and coupled to proteins to be effective agents. The use of specially selected gold-clusters with specially selected ligands which are not bound to proteins has never been considered in Hainfeld et al. Thus, in view of the Hainfeld et al. reference, it has not been obvious to those skilled in the art to use specially selected gold-clusters with specifically selected ligands as

antitumor agents. According to Hainfeld et al., only protein labeled gold-clusters are deemed to be effective.

Peschel et al. reference (S. Peschel and G. Schmid, Angew. Chem. Int. Ed. Engl., 1995, 34, No. 13/14)

This reference describes the preparation of monolayers of ligand-stabilized gold-clusters on an poly(ethyleneimine) coated carrier.

It has already been stated in a prior Response that the Peschel et al. reference cannot be compared to the present invention since no medical application of the gold-clusters is envisaged in Peschel et al.

The rejections raised by the Examiner regarding pending Claims 50, 51 and 61 to 63 based on Peschel et al. should be overcome by the amendments to the claims. The amended claims do not claim the specially selected gold-clusters per se, but they rather claim this gold-clusters being formulated for the therapeutic treatment of neoplastic and cancerous disorders of the human and animal body (i.e. in other words, the respective pharmaceutical compositions).

Therefore, the Peschel et al. reference cannot be regarded to be novelty-destroying in view of the claimed formulation for treatment.

Furthermore, one skilled in the art cannot get any hint in order to arrive at the claimed formulation for treatment from the Peschel et al. reference since Peschel et al. does not envisage at all any therapeutic use, let alone the specific therapeutic use of the present invention.

Since the Peschel et al. reference cannot be compared to the claimed formulation for treatment and the Hainfeld et al. reference leads away from the claimed formulation for treatment, even a combination of the Hainfeld et al. reference over Peschel et al. would not lead one of ordinary skill in the art to the claimed formulation for treatment as well.

In view of the amending changes and the foregoing remarks, claims 50-55 and 61-63 are in condition for allowance and such action by the Examiner is respectfully requested.

Respectfully submitted,

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